EXHIBIT C
Part 2 of 2

No Evidence That Any Jobs Will Be Lost

- No sales and no manufacturing by Shionogi – so very few employees work on Fortamet®
- Not mentioned in business reports projecting decline in the market
- Shionogi U.S. 2010 net sales were $250 million without Fortamet®

SHIO 019411, Tab 22

- Shionogi U.S. has pipeline of at least eight new products

www.shionogi.com/shionogiinc/research-development, Tab 23

  - Including one nearing market (ospemifene)

The Balance of Hardships Does Not Favor Shionogi

- Standard is to "balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the nonmoving party will incur if the injunction is granted"

Novartis Corp. v. Teva Pharms., 2007 WL 1695689 (D.N.J. June 11, 2007), quoting *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988)

- Shionogi already gave up on the Fortamet® market
  - Steady decline
  - Stopped promotions one year ago
  - Failure to provide 500 mg for a year
- Authorized generic can – and probably will – enter market regardless of Lupin's continued presence
  - Shionogi will get 70% royalties from authorized generic sales
  - License Agreement gives Shionogi no control over authorized generic
- Lupin will lose
  - 180-day exclusivity
  - Benefit from filing ANDA one year before next generic competitor
  - 500 mg market may not exist by the time a trial is held
  - Damage to reputation from not being permitted to honor contracts

The Public Interest Favors Lupin

- Public interest in availability of low-priced, generic drugs
  - Public interest in availability of 500 mg dosage
- Public interest in enforcement of valid patent
  - But here, claims in printed patent were not ultimately allowed
  - No public interest in enforcement of patent that was not allowed by the PTO

Preliminary Injunction Standard

Four factors:

- Reasonable likelihood of success on the merits
- Irreparable harm if not granted
- Balance of hardships tipping in favor of movant
- Favorable impact on public interest

See, e.g., Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001)

Preliminary Injunction Standard

- Shionogi must show likelihood of success on the merits and irreparable harm for injunction to be granted
  - "Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes both of the first two factors...."

Amazon.com, 239 F.3d at 1352;
Altana Pharma AG v. Teva Pharm. USA, Inc., 566 F.3d 999, 1005 (Fed. Cir. 2009)

Preliminary Injunction Standard

- Burden of proof remains on movant/patentee, even for those arguments where trial burden of proof will be on generic
  - "[T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent."

    Amazon.com, Inc., 239 F.3d at 1350-51, quoted by *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, 2010 U.S. Dist. LEXIS 59236 (D.N.J. June 14, 2010)
  - "[A]t the preliminary injunction stage, because of the extraordinary nature of the relief, the *patentee* carries the burden...."

    Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original)

Preliminary Injunction Standard

- "To defeat plaintiffs' [preliminary injunction] motion, [a generic company] need not prove non-infringement or invalidity; [it] merely needs to raise a substantial question concerning either infringement or invalidity, *i.e.*, assert an infringement or invalidity defense that Plaintiffs cannot prove lacks substantial merit."

King Pharm. Inc. v. Sandoz, Inc., C.A. No. 08-5974, 2010 WL 1957640, at *1 (D.N.J. May 17, 2010) (Brown, Ch.J.) (not for publication) (quoting *Amazon.com*, 239 F.3d at 1350-51)

- "Plaintiff must provide a 'clear showing' that it will suffer irreparable harm in the absence of injunctive relief."

King Pharm. v. Sandoz, 2010 WL 1957640 at *5 (citing *Nutrition 21*, 930 F.2d at 870-71)

- "Irreparable harm must be established as a separate element, independent of any showing of likelihood of success; irreparable harm can no longer be presumed."

King Pharm. v. Sandoz, 2010 WL 1957640 at *5 (citing *Nutrition 21*, 930 F.2d at 870-71)

Injunction Is Extraordinary Remedy

- A preliminary injunction in Hatch-Waxman pharmaceutical cases is a "drastic and extraordinary remedy that is not to be routinely granted"

King Pharm., 2010 WL 1957640, at *1

- Damages are the norm in patent cases
- Courts use many different approaches
- Shionogi's agreement with Watson/Andrx demonstrates Plaintiff's attitude toward compensation for generic competition outside the context of litigation – license and royalty is sufficient

Shionogi's Accusations Against Lupin Are Baseless

- There was no inappropriate "stealth" launch
  - Does Macy's tell Gimbels?
- Lupin did not "flood" the market
  - Three-month supply not unusual for launch
- Lupin's product is not "inferior" to the brand product
  - FDA supervision and factory inspection
  - Manufacturing "issue" identified and resolved rapidly
    - Watson's unidentified "manufacturing issue" kept product off the market for a year – presumably does not mean 1,000 mg or the recently reintroduced 500 mg are "inferior"

Recall Is Unwarranted

- Extraordinary remedy
- Extreme harm to Lupin
- Burdensome and expensive
- Ineffective – especially given Shionogi's delay
- No evidence that any future harm will be forestalled by recall
- Almost never granted in absence of public health risk

Shionogi Does Not Dispute Lupin's Main Conclusions Showing There Is No Irreparable Injury

- Neither Vellturo nor Shionogi contradict Lupin's main conclusions which demonstrate there is no irreparable harm:
  - All claimed harms are quantifiable
  - Shionogi ceased promoting Fortamet® in August 2010, despite decline in sales and projected additional decline in sales
  - Shionogi Japan is unlikely to shut down U.S. operations given $250 million net sales from non-Fortamet® products
    - Conclusion further supported by statements in Shionogi 2011 Annual Report and October 28, 2011 press release
  - If no injunction now, damages can be no more than size of Fortamet® franchise, which is known
    - Difficulty in allocating cause of lost sales among generic competitors does not make harm unquantifiable
- Instead, Shionogi and Vellturo's criticisms are minor and inaccurate

Criticisms by Shionogi and Its Expert Vellturo Against Lupin's Experts Gleason and Hofmann Are Baseless

- Vellturo asserts that Gleason and Hofmann are incorrect that Shionogi will not be required to decrease prices to meet generic competition

Vellturo Decl., ¶ 22

But

- Shionogi has raised its prices steadily over the past several years
- Shionogi raised its prices on November 8, 2011, after Lupin launched

25% for 1,000 mg, 62% for 500 mg

LUP 0066406-413, 0066418, Tab 20

- The difference in profits between two different prices is quantifiable

Criticisms by Shionogi and Its Expert Vellturo Against Lupin's Experts Gleason and Hofmann Are Baseless

- Vellturo asserts that Gleason and Hofmann contradict themselves between paragraphs 49 and 51 concerning whether the brand will control the authorized generic

Vellturo Decl., ¶ 26

But

This is based on a misquotation of Gleason and Hofmann's declaration:

- G/H in paragraph 49 actually say: "We also understand that Watson's AG may not be forced to exit the Fortamet® market if the preliminary injunction is granted. Often times…[i]f the third party generic pharmaceutical company is forced to withdraw its product from the market, **the AG company** would likely also exit at the direction of the branded company. However, the AG arrangement between Watson and Shionogi is slightly different"
- G/H in paragraph 51 state: "Whether or not Watson will remain on the market is unknown" (and it continues to point out that Vellturo does not discuss the effect of the Watson presence on the market in claiming irreparable injury that can be cured by enjoining Lupin)
- Vellturo distorts this by replacing "the AG company" – words clearly general and not referring to Watson – with "[Watson]," and then asserting that the two statements are inconsistent

Criticisms by Shionogi and Its Expert Vellturo Against Lupin's Experts Gleason and Hofmann Are Baseless

- Vellturo attacks Gleason and Hofmann as inconsistent because they say a recall would be onerous and also would be ineffective, given that most of Lupin's product already has been sold

Vellturo Decl., ¶ 27

But

- A recall is onerous because one has to contact all of the wholesale and retail outlets, regardless of whether there is product to be retrieved

Gleason/Hofmann Decl., ¶ 58-60, Tab 24; Hoffman Decl., ¶ 27-29, Tab 4

Criticisms by Shionogi and Its Expert Vellturo Against Lupin's Experts Gleason and Hofmann Are Baseless

- Vellturo ignores Shionogi's own statements that the Fortamet® market is in decline, and asserts that Lupin would not have launched if it thought the market was declining

But

- Contradicted by his own Footnote 11 suggesting Fortamet® might be removed from the market before the patent expires
- One reason for having to launch now is that, given Shionogi's failure to support Fortamet®, the market might be destroyed before trial if no one – such as a generic competitor – works to support it

Hoffman Decl., ¶ 4, 23-24, Tab 4

Criticisms by Shionogi and Its Expert Vellturo Against Lupin's Experts Gleason and Hofmann Are Baseless

- Vellturo asserts that Gleason and Hofmann are inconsistent by saying both that damages are quantifiable and that they would not accept Shionogi's market figures without further analysis

Vellturo Decl., ¶ 24

But

- Saying the information exists and damages can be quantified does not mean one must accept without question accuracy of figures being advanced by opposing party; disagreement does not mean unquantifiable
- Passage of time and actual sales data will give quantifiable damages

Conclusion

- Shionogi has not advanced any reason that Gleason and Hofmann's analysis and conclusions should not be accepted by this Court
- The burden is on Shionogi to prove it deserves this extraordinary remedy
- Shionogi falls far short of meeting its burden
- Preliminary injunction and recall should be denied